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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,456	02/13/2004	Peter Strong	672601-2001	9496

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,456	STRONG, PETER	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *4,6,7,10-27 and 37-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8,9 and 28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *notice to comply*.

DETAILED ACTION

1. Claims 1-43 are pending.

2. Applicant's election with traverse of Group I, claims 1-9 and 28-36 drawn to a method of treating an allergy and aeroallergens as elected species in the reply filed on 6/19/06 is acknowledged.

Applicants traversed the restriction requirement and species election based on that there is no serious search burden imposed. This is not found persuasive because the pending claims of each group from the original restriction are patentably distinct methods as referred in this restriction requirement. It is undue burden to search more than one invention.

A prior art reads on method for treating allergy differs from a prior art reads on method for treating cancer. In addition, a prior art reads on ragweed (e.g. aeroallergen) differs from a prior art reads on food allergen. The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 4, 6, 7, 10-27 and 37-43 are withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention/species.

Claims 1-3, 5, 8, 9 and 28-36 read on elected species of aeroallergen are being examined.

3. Applicant's IDS filed 4/6/04 and 2/26/06 have been acknowledged.

4. Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) is acknowledged. However, the certified copies of priority documents have not been provided.

5. The use of trademarks has been noted in this application (e.g. CYTOPERM® on p. 21 FACSCAN® on p. 21, CELLQUEST ® on p. 21, FLUROTHANE ® on p.23). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent application, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks

6. This application contains a sequence disclosure that is encompassed by the definition of amino acid sequence set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirement of 37. CFR. 1.821 through 1.826 for the reasons set forth herein.

It is noted that the amino acid sequence disclosed in p. 19 of the instant specification needs to be accompanied by SEQ ID NO. Applicant is reminded of the sequence rules which require a submission for all sequences of more than 10 nucleotides or 4 amino acids (see 37. CFR. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules. Applicant is required to amend the specification accordingly.

7. Claims 2-3 are being objected to because of the following informalities: the phrase " group comprising... or" in claims 2-3 should be changed to "group consisting of ... and".

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 34 is rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "active compound" recited in claim 34 is unclear. The chitin microparticle preparations used in a method of treating allergy comprises chitin microparticles and an allergen. It is not clear if the active compound refers to chitin microparticles or allergen.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 5, 8, 9 and 28-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating allergy to aeroallergen by intranasal administration of chitin microparticles in mice, does not reasonably provide enablement for a method of treating allergy to any allergen or allergy treatable by reducing serum IgE, and by allergic desensitization and a method of treating allergy by administering chitin microparticles in humans or in horses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

The specification does not reasonably provide enablement for treating any allergy conditions by administering chitin microparticles intranasally and how to practice the invention as claimed without undue experimentation. The claims are directed to a method for treating allergy by administering chitin microparticles intranasally. However, specification as filed fails to provide sufficient guidance with respect to treating allergy by chitin microparticles intranasally other than allergy caused by house dust mite and fungal spores, *Dermatophagoides pteronyssinus* and *Aspergillus fumigatus*, respectively.

Merck Manual of Diagnosis and Therapy recognizes that the hypersensitivity refers to pathological processes that result from immunologically specific interactions between allergens and suggests different methods of treatment based on specific allergens (p. 1041-1058, in particular). In addition, treatment for allergic rhinitis (p. 1048, in particular) is different from treatment of food allergy. Generally recognized antihistamine method is not indicated (p. 1052, in particular) in treatment of food allergy with few exceptions. Thus, there is no universal allergy treatment effective to any allergens.

In addition, Applicant fails to provide any in vivo working example for treating any allergies other than allergy to aeroallergens by administering chitin microparticles in humans or in horses.

To summarize, reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view or the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-3, 5, 8 and 28-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata et al. (IDS reference AQ) in view of Clinical Report (Pediatrics, 1997, vol. 100(1):143-152) as is evidenced by the specification of the instant application on p. 19 and Sigma Chitin powder product sheet.

Shibata et al. teach a method of treating an allergy by aeroallergen such as ragweed by administering chitin microparticles (N-acetyl –D-glucosamine) in saline (e.g. a buffer) having diameter of 1-10um into mice (abstract, p. 1320, in particular) and this method is clinically relevant to human therapy (p. 1314, 1320, in particular).

Shibata et al. further teach prophylactic effects of chitin administration, ragweed desensitization (p. 1316, in particular) and chitin induces Th1 cytokines (e.g. IFN-g) which down regulate allergic airway inflammation (p. 1318, discussion, in particular).

Claims 31 and 32 are included because the prior art chitin powder has been purchased from Sigma-Aldrich as well as the claimed chitin powder as is evidenced by the specification of the instant application p. 19. The source of both chitin powder is crab shell and prepared by art-recognized method such as milling. Furthermore, due to the lack of definition of "active compound" in claim 34, the effective amount of 0.01-100mg/kg body weight reads on 100ug of ragweed allergen per mice having body weight of 20g (Table 3, p. 1315).

Shibata et al. do not teach intranasal/nasal administration of chitin microparticles as in claim 1.

However, Clinical Report teaches that nasal /intranasal administration is a well recognized route of administration for delivering drugs in allergy treatment such as corticosteroid or antihistamine and nasal musosal surface provides a rapid and relatively painless drug absorption resulting in rapid central nervous system effect (p.5-7, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ intranasal or nasal delivery method in allergy treatment as taught by the Clinical Report in the method of treating allergy as taught by Shibata et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the Clinical Report teaches that the nasal/intranasal method of delivering drugs in allergy treatment provides rapid and painless drug absorption.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
July 25, 2006

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No. 10/779,456	Applicant(s) Strong, Peter
	Examiner KIM	Art Unit 1644

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Amino acid sequence disclosed in p.19 of the specification needs to be identified by SEQ ID NO.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

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